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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,425	BASSLER ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36 and 39-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2-9,23,26,33-35 and 45-48* is/are allowed.

6)☒ Claim(s) *1,10-22,24,25,27-32, 36, 39, 42 and 43* is/are rejected.

7)☒ Claim(s) *40,41 and 44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-36 and 39-48 are presented for examination.

Applicants' amendment filed February 6, 2006 has been received and entered.

Accordingly, the rejections made under 35 USC 112, first paragraph and 35 USC 112, second paragraph as set forth in the previous Office action dated October 14, 2005 at pages 4-9 are hereby withdrawn.

Allowable Subject Matter

Claims 2-9, 23, 26, 33-35 and 45-48 are allowable.

Claim Objections

Claims 40, 41 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention

made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is again rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,559,176. Although the conflicting claims are not identical, they are not patentably distinct from each other because of record, for reason of record as set forth in the previous Office action dated October 14, 2005 at page 3 as applied to claim 1.

Applicants' remarks regarding the Examiner did not explain why the present application is an obvious variant of the patented application are not persuasive since the patented application teaches a method for regulating the activity of an autoinduce-2 receptor comprising contacting an autoinducer-2 receptor with an AI-2 agonist or antagonist compound; and the present application teaches a method for identifying a compound (an AI-2 agonist or antagonist) that regulates the activity of autoinducer-2. Clearly, the present application needs the patented application in order for is to work. Also no rejection was made in the patented application to identify the two inventions to be separate.

The rejection made under obviousness-type double patenting is adhered to.

Claim 1 is not allowed.

Claim 1 is again rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,936,435. Although the conflicting claims are not identical, they are not patentably distinct

from each other because of record, for reason of record as set forth in the previous Office action dated October 14, 2005 at pages 3-4 as applied to claim 1.

Applicants' remarks regarding the present application's method is different from the patent application' method are not persuasive since the specification of the patented application (column 15, lines 8-29) states the selecting inhibitor or synergists of the autoinducer-2 molecule. In order to produce synergy, a person must have two or more compounds (a mixture). Clearly, present application encompasses the patented application because the present application is broad and the patented application is narrowed. Therefore, the patented application is taught by the present application.

The rejection made under obviousness-type double patenting is adhered to.

Claim 1 is not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-18, 36, 39, 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is rendered indefinite by the phrase "providing a bacterial cell, or extract there of, comprising biosynthetic pathways". This phrase does not definite any specific extract, or any specific pathways that structurally define any specific molecules that evidence the recited functional characteristics. While the

specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide structural properties to allow for one to identify what is being claimed.

Claim 11 is rendered indefinite by the phrase "wherein the autoinducet-2 is endogenous autoinducer-2" and depends on claim 10 which recite two different types of autoinducer-2, specifically an autoinducer-2 analog and an autoinducer-2. Which of the two types of autoinducer-2 recited in claim 10 does the endogenous autoinducer-2 phrase refer?

Claim 13 is rendered indefinite by the phrase "wherein the autoinducet-2 is exogenous autoinducer-2" and depends on claim 10 which recite two different types of autoinducer-2, specifically an autoinducer-2 analog and an autoinducer-2. Which of the two types of autoinducer-2 recited in claim 10 does the exogenous autoinducer-2 phrase refer?

The remaining claims are rendered indefinite to the extent that they incorporate the above terminology.

Claim 36 is rendered indefinite by the phrase "contacting at least one bacterial cell with an autoinducer molecule under conditions and for such time as to promote induction of a bacterial biomarker". This phrase does not definite any specific bacterial cell.

Claim 39 is rendered indefinite by the phrase "contacting at least one cell with an autoinducer molecule under conditions and for such time as to promote induction of a bacterial biomarker". This phrase does not definite any specific cell.

Claim 42 is rendered indefinite by the phrase "a compound that affects autoinducer-1 binding to an autoinducer-2 receptor". This phrase does not definite what compound is used. While the specification can be used to provide definitive support, the claim is not read in a vacuum. Rather the claim must be definite and complete in and of itself. Claim 42 is also indefinite by the phrase "providing a cell, or cell extract there of, comprising biosynthetic pathways". This phrase does not definite any specific cell extract, or any specific pathways that structurally define any specific molecules that evidence the recited functional characteristics. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide structural properties to allow for one to identify what is being claimed. Claim 43 is rendered indefinite to the extent that it incorporates the above terminology.

Claims 10-18, 36, 42 and 43 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-22, 24, 25 and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuo et al. (J. Bacteriology, Feb 1996, Vol. 178(4), pp. 971-975.

Kuo et al. teach a method of identifying an autoinducer analog that regulates activity of the autoinducer, the method comprising the steps of:

a) contacting a bacterial cell (mutant strain of Vibrio fischeri, mutant strain only defective in ainS (see abstract, lines 9-10)) with an autoinducer analog, AI-2 exogenous source of autoinducer AI-2, see abstract, line 1);

b) comparing the amount of light produce by the bacterial cell in the presence of an autoinducer (parent strain able to produced both AI-1 and AI-2) with the amount of light produced in the presence of the autoinducer analog (AI-2, is an analog of AI-1(the two molecules are competitively interact with each other, see page 975, column 1, paragraph at top of the page, last sentence);

the mutant strain produce accelerated luminescence induction as compared to the parent strain upon contact with the exogenous source AI-2 analog, wherein a change in the production of light is indicative of an autoinducer analog that regulates activity of an autoinducer.

Note the control strain MJ-100, produced endogenous autoinducers, being both lux+/ainS+, AI-1 being an analog of AI-2; and AI-2 being an analog of AI-1 (see Figure 1). The luminescence of the strain was indicative of the presence of autoinducer analogs. The assay was carried out in vitro (under laboratory conditions, see Figure 2, page 973, column 1). The assay was carried out in vivo (within a bacterial cell,

through detection of luminescence induction (see Figure 1, page 973 and Figure 3, page 973, column 2, top of the page). Wherein the regulation is by inhibition of autoinducer activity (see page 973, column 2, paragraph 2, last sentence; and paragraph 3, last sentence; also see abstract, last three lines).

The reference anticipates the instant invention, therefore, the instant invention is unpatentable.

Claims 10-22 and 27-32 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al. (J. Bacteriology, Feb 1996, Vol. 178(4), pp. 971-975.

Kuo et al. were discussed above supra a method of identifying an autoinducer analog that regulates activity of the autoinducer, the method comprising the steps of:

a) contacting a bacterial cell (mutant strain of Vibrio fischeri, mutant strain only defective in ainS (see abstract, lines 9-10)) with an autoinducer analog, AI-2 exogenous source of autoinducer AI-2, see abstract, line 1);

b) comparing the amount of light produce by the bacterial cell in the presence of an autoinducer (parent strain able to produced both AI-1 and AI-2) with the amount of light produced in the presence of the autoinducer analog (AI-2, is an analog of AI-1(the two molecules are competitively interact with each other, see page 975, column 1, paragraph at top of the page, last sentence).

The instant invention differs from the cited reference in that the cited reference does not teach the compound that affects autoinducer-2 binding to an autoinducer-2 receptor. However, one skilled in the art would have assumed that the function of the cited reference, Kuo et al., would affect the autoinducer-2 binding to an autoinducer-2 receptor in the absence of evidence to the contrary.

Claims 42 and 43 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:00 am-8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
May 8, 2006